

R&D

Bausch + Lomb

ULOTKA PIL

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Nazwa produktu

Product Name

Biotrue rewetting drops

Kolor nadruku Colours

Black

Kraj

Country (ISO)

CA

Nr wykrojnika

Spec No

14842

Opracowane przez

Designed by

Shelby Fleskes
shelby.fleskes@bausch.com
(720) 532-5862

Kod Wytwórcy

Manufacturer code

43075PB931/3-CA

Nr korekty

Proof No

4

Data

Date

12.07.2023

Kod farmaceutyczny

Pharmacode

316

Kod wersji

Valeant version code

P1CA03

Inny kod

Other code

-

Rozmiar czcionki

Font size

minimum 8 pt

Wymiar ulotki

PIL size

148 x 420 mm

Krój czcionki

Font used

Interstate Font Family
Arial Font Family

Gramatura papieru

Paper weight

- g/m²

Komentarze Comments (Reason for the change)

-PMR_BNL-23-0148-A

-Reference: LCRF-2023-005 - Biotrue Eye Drops 10ml

Canada Med Device Artwork Updates (remove „Laval, Quebec“ statement) + graphic updates

Factory (Packing site): DMP Berlin

Akceptacja Techniczna Technical Approval

GENEHMIGT

Von Franka Bessem , 14:01, 13.07.2023

Akceptacja Działu ds. Rejestracji Regulatory Affairs Dept. Approval

APPROVED

By Brando Santini at 9:07 am, Jul 13, 2023

APPROVED

By Cecile Cualing at 4:13 pm, Aug 02, 2023

Please read these instructions for use carefully - they contain important information on how to use this product. If you have any questions, please ask your eye care professional or contact us.

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Bio
true[®]
eye drops

Inspired by the nature of your eyes

What is Biotrue[®] eye drops?

Biotrue[®] eye drops is a preservative free clear eye drop solution that contains 0.24% of the clinically proven natural moisturizer hyaluronic acid (as sodium hyaluronate), found in the structures of a healthy human eye and the natural tear film. Biotrue[®] eye drops provide instant soothing and natural hydration. The product refreshes and calms dry eyes, relieving symptoms of tired, stressed, burning and teary eyes. It provides instant comfort, long-lasting moisture and protection from everyday stresses. This product is suitable for the wetting and rewetting of both soft and rigid contact lenses during wearing, and noticeably improves the comfort of the contact lenses. It can be also used post-LASIK surgery. Biotrue[®] eye drops formulation possesses a very high tolerability as it is free of preservatives. It is presented in the innovative preservative free multi-dose system (PFMD), which is easy and safe to use. Once the bottle is opened, it can be used for up to 6 months.

When should you use Biotrue[®] eye drops?

Biotrue[®] eye drops is designed to remain on the surface of the eye, instantly moisturizing it to relieve dry eye symptoms. It is an ideal product for people suffering from a range of symptoms of dry eyes, such as tired, stressed, burning or teary eyes.

Dry eyes can be caused by a number of factors, both physical and environmental:

- external factors, such as prolonged use of digital devices, air conditioning, heating, cigarettes smoke, windy outdoor environments as well as wearing contact lenses;
- LASIK surgery;
- taking certain drugs, such as birth control pills, antihistamines, high blood pressure medicines, heart medicines, pain relievers, anti-inflammatories and diuretics;
- certain diseases that play a role in the development of ocular dryness, such as diabetes, rheumatoid arthritis, or thyroid problems.

Biotrue[®] eye drops are also available in a preservative free single dose 30-unit format.

How often and for how long should you use Biotrue[®] eye drops?

Instill 1 or 2 drops of Biotrue[®] eye drops in the eye as needed. Its preservative free formulation makes the product suitable to use every day and as often as needed throughout the day. Biotrue[®] eye drops can be used for as long as needed. If you are using this product for post-operative (e.g. LASIK) dryness and discomfort, follow your eye doctor's instructions.

What ingredients does this product contain?

0.24% sodium hyaluronate, sodium chloride, potassium chloride, disodium phosphate dodecahydrate, sodium dihydrogen phosphate-dihydrate, water for injection.

How to use Biotrue[®] eye drops?

The patented pump mechanism of the Biotrue[®] eye drops bottle allows the eye drop solution to be preservative free, safe and easy to use.

- Before each use, wash your hands and remove the protective cap from the tip of the bottle with a rotating movement. Avoid contact of the tip of the bottle with your fingers or any other surfaces to prevent any possible contamination of the solution.
- Attention! Before first use and if the bottle has not been used for a while:** Point the bottle with the tip downwards and press the pump mechanism repeatedly until a drop is released. Now the bottle is ready to use.

- Hold the bottle as indicated: place your thumb on the ergonomic thumb support, grip the lower part of the bottle with your fingers and place two fingers on the bottom of the bottle.
- Lean your head back slightly and gently pull your lower eyelid down with a finger of your free hand. Hold the bottle, as described in the step above, in a vertical position over your eye and gently press the pump mechanism to apply one drop into the eye.

Avoid touching the surface of your eye with the bottle tip to prevent any possible injury and/or contamination of the solution.

Close your eye afterwards, slowly move it back and forth and then blink your eyes in order to optimally spread the drop on the surface of your eye.

Immediately after use, shake off any possible residual drops and place the protective cap back on the dry tip of the bottle. The Biotrue[®] eye drops bottle releases 10 mL of eye

drop solution. Due to the bottle design, a small amount of additional solution remains in the bottle.

When should you not use Biotrue[®] eye drops?

Do not use this product if you are hypersensitive to any of its ingredients.

Important information about using Biotrue[®] eye drops:

- Biotrue[®] eye drops should not be used if you are hypersensitive to any of its ingredients.
- Local hypersensitivity reactions have been very rarely reported. Treatment should be discontinued in such cases. If you experience persistent discomfort or irritation, stop using the product and consult your doctor.
- Safety information for patients with severe damage of the cornea: In very rare cases, deposits of calcium phosphate on the cornea have been reported during treatment with phosphate-containing products for ophthalmic use.
- Do not touch the eye surface with the tip of the bottle to prevent any possible injury of the eye surface and/or contamination of the solution.
- Once opened, do not share the bottle with anyone else.
- Careless use of the product contrary to the instructions for use could result in slipping of the product from hand and may cause eye injury.
- Shake off any possible residual drops after application.
- Wait approximately 15 minutes before using another eye product.
- Biotrue[®] eye drops can be used for up to 6 months after the bottle is opened and the bottle should be discarded after that time. To help you remember, the label on the bottle has a space where you can note when the bottle was first opened.
- Do not use beyond expiry date.
- Do not use if product packaging and/or bottle are damaged.
- Biotrue[®] eye drops is filled in a bottle with small plastic parts that could be swallowed by small children. Danger of suffocation. Therefore, Biotrue[®] eye drops should be kept out of reach of children.

How to store Biotrue[®] eye drops?

Store between +1°C and +25°C.

	Dr. Gerhard Mann Chem.-pharm. Fabrik GmbH, Brunsbütteler Damm 165/173, 13581 Berlin, Germany		Discard the bottle 6 months after opening it for the first time.
	Store between +1°C and +25°C.		Batch code
	Do not use if product packaging and/or bottle are damaged		Sterilization method, aseptic
	Expiry date		Caution: Consult the "Instructions for use" for important cautionary information, such as warnings and precautions
	Consult instructions for use		

Questions? 1-888-459-5000

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MANUFACTURER COUPON

Save \$3.00

on any one (1) Bausch + Lomb Biotrue[®] eye drops

CONSUMER: Valid at participating retailers and pharmacies only. Coupon must be presented to cashier at time of purchase. Offer cannot be combined with any other offer.

DEALER/RETAILER: Upon presentation of this coupon by your customer toward the purchase of the specified product, Bausch + Lomb Canada will reimburse the face value of the coupon plus regular handling fee provided you accept it from your customer on purchase of item specified. Other applications may constitute fraud. Failure to send in, on request, evidence that sufficient stock was purchased in previous 90 days to cover coupons presented will void coupons. Coupons submitted become our property. Reimbursement will be made only to retail distributor who redeemed coupon. A reduction in any applicable taxes payable is included in the coupon face value. For redemption, mail to: Bausch + Lomb Canada, PO Box 31000, Scarborough, ON, M1R 0E7.

Expiry date: December 31, 2025

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true[®]
eye drops

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7/12/23 8:53 AM

R&D

Bausch + Lomb

ULOTKA PIL

BAUSCH + LOMB

Nazwa produktu

Product Name

Biotrue rewetting drops

SDU

Kolor nadruku

Colours

Black

Kraj

Country (ISO)

CA

Nr wykrojnika

Spec No

14842

Opracowane przez

Designed by

Shelby Fleskes

shelby.fleskes@bausch.com

(720) 532-5862

Kod Wytwórcy

Manufacturer code

43081PB764/3-CA

Nr korekty

Proof No

2

Data

Date

18.07.2023

Kod farmaceutyczny

Pharmacode

102

Kod wersji

Valeant version code

P9CA02

Inny kod

Other code

-

Rozmiar czcionki

Font size

minimum 8 pt

Wymiar ulotki

PIL size

148 x 420 mm

Krój czcionki

Font used

Interstate Font Family

Gramatura papieru

Paper weight

- g/m²

Komentarze

Comments (Reason for the change)

-PMR_BNL-23-0202-A

-Reference: LCRF-2023-006 - Biotrue Eye Drops 15 and 5 ml - Canada Med Device Artwork Up-dates (remove „Laval, Quebec“ statement) + graphic updates

Factory (Packing site): DMP Berlin

Akceptacja Techniczna

Technical Approval

GENEHMIGT

Von Franka Bessem , 09:21, 21.07.2023

Akceptacja Działu ds. Rejestracji

Regulatory Affairs Dept. Approval

APPROVED

By Brando Santini at 10:06 am, Jul 24, 2023

APPROVED

By Cecile Cualing at 4:11 pm, Aug 02, 2023

Please read these instructions for use carefully - they contain important information on how to use this product. If you have any questions, please ask your eye care professional or contact us.

BAUSCH + LOMB

Biotrue[®]
eye drops
single dose

Inspired by the nature of your eyes

What is Biotrue[®] eye drops single dose?

Biotrue[®] eye drops single dose is a preservative free clear eye drop solution that contains 0.2% of the clinically proven natural moisturizer hyaluronic acid (as sodium hyaluronate), found in the structures of a healthy human eye and the natural tear film. Biotrue[®] eye drops single dose provides instant soothing and natural hydration. The product refreshes and calms dry eyes, relieving symptoms of tired, stressed, burning and teary eyes. It provides instant comfort, long-lasting moisture and protection from everyday stresses. This product is suitable for the wetting and rewetting of both soft and rigid contact lenses during wearing, and noticeably improves the comfort of the contact lenses. It can be also used post-LASIK surgery. Biotrue[®] eye drops single dose formulation is preservative free, possessing a very high tolerability. It is presented in a convenient and easy to use single-dose format.

When should you use Biotrue[®] eye drops single dose?

Biotrue[®] eye drops single dose is designed to remain on the surface of the eye, instantly moisturizing it to relieve dry eye symptoms. It is an ideal product for people suffering from a range of symptoms of dry eyes, such as tired, stressed, burning or teary eyes.

Dry eyes can be caused by a number of factors, both physical and environmental:

- external factors, such as prolonged use of digital devices, air conditioning, heating, cigarettes smoke, windy outdoor environments as well as wearing contact lenses;
- LASIK surgery;
- taking certain drugs, such as birth control pills, antihistamines, high blood pressure medicines, heart medicines, pain relievers, anti-inflammatories and diuretics;
- certain diseases that play a role in the development of ocular dryness, such as diabetes, rheumatoid arthritis, or thyroid problems.

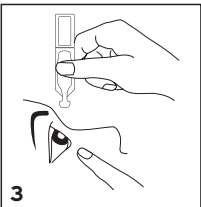
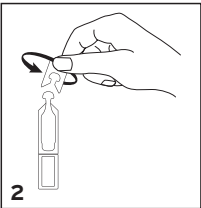
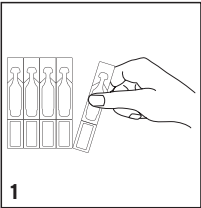
Biotrue[®] eye drops are also available in an innovative preservative free multi-dose 10 mL bottle.

How often and for how long should you use Biotrue[®] eye drops single dose?

Instill 1 or 2 drops of Biotrue[®] eye drops single dose in the eye as needed. Discard the single-dose unit immediately after use. The product's preservative free formulation makes it suitable to use every day and as often as needed throughout the day. Biotrue[®] eye drops single dose can be used for as long as needed. If you are using this product for post-operative (e.g. LASIK) dryness and discomfort, follow your eye doctor's instructions.

How to use Biotrue[®] eye drops single dose?

The illustrations show how simple and easy it is to use the Biotrue[®] eye drops single dose.



1. Holding it as shown on the illustration, separate one single-dose unit from the strip.

2. Twist the top cap off the single-dose unit.

3. Lean your head back slightly and gently pull your lower eyelid down with a finger of your free hand. Hold the single-dose unit as vertically as possible above your eye with the nozzle pointing downwards and then gently squeeze the single-dose unit to apply one drop into the eye.

Close your eye afterwards, slowly move it back and forth and then blink your eyes in order to optimally spread the drop on the surface of your eye.

Avoid contact of the tip of the single-dose unit with your eyes or fingers to prevent any possible contamination of the solution and/or eye injury.

What ingredients does this product contain?

0.2% sodium hyaluronate, sodium chloride, potassium chloride, disodium phosphate dodecahydrate, sodium dihydrogen phosphate-dihydrate, water for injection.

When should you not use Biotrue[®] eye drops single dose?

Do not use this product if you are hypersensitive to any of its ingredients.

Important information about using Biotrue[®] eye drops single dose:

- Biotrue[®] eye drops single dose should not be used if you are hypersensitive to any of its ingredients.
- Safety information for patients with severe damage of the cornea: In very rare cases, deposits of calcium phosphate on the cornea have been reported during treatment with phosphate-containing products for ophthalmic use.
- Avoid contact of the tip of the single-dose unit with your eyes or fingers to prevent any possible injury of the eye and/or contamination of the solution.
- Each single-dose unit should be immediately discarded after use.
- Wait approximately 15 minutes before using another eye product.
- Do not use beyond expiry date.
- Do not use if product packaging and/or single-dose units are damaged.

How to store Biotrue[®] eye drops single dose?

Store between +1°C and +25°C.

	Dr. Gerhard Mann Chem.-pharm. Fabrik GmbH, Brunsbütteler Damm 165/173, 13581 Berlin, Germany		Consult instructions for use
	Store between +1°C and +25°C.		Use single-dose units only once.
	Do not use if the product packaging and/or single-dose units are damaged.		Batch code
	Expiry date		Sterilized using aseptic processing techniques and packaged in a single sterile barrier system.

Questions? 1-888-459-5000

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Expiry date: December 31, 2025

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